

## **Bylaws of the Scientific and Medical Research Funding Working Group**

### **ARTICLE 1. Authority.**

The Scientific and Medical Research Funding Working Group (“SMRFWG”) of the Independent Citizen’s Oversight Committee (“ICOC”) to the California Institute for Regenerative Medicine (“Institute”) is established by Part 5, Division 106, Chapter 3, section 125290.50 and section 125290.60 of the Health & Safety Code, also known as the California Stem Cell Research and Cures Bond Act (“Act”).

### **ARTICLE II. Purpose.**

The SMRFWG is created for the purpose of recommending standards, criteria and grant and loan awards to the ICOC. This purpose will be accomplished through the review of grants and loan applications, based on standards and criteria adopted by the ICOC, in order to make recommendations to the ICOC for the award of training, research, therapy development, and clinical trial grants and loans. Finally, this purpose will be accomplished through oversight reviews of grantees to ensure compliance with the terms and conditions of the award in order to fulfill the mission of the Act, and to make recommendations for subsequent actions to the ICOC.

### **ARTICLE III. Functions.**

The duties of the SMRFWG shall include the following:

- (A) Recommend to the ICOC interim and final criteria, standards and requirements for considering funding applications and for awarding grants and loans;
- (B) Recommend to the ICOC standards for the scientific and medical oversight of awards;
- (C) Recommend to the ICOC any modifications of the criteria, standards and requirements described in sections (A) and (B) above as needed;
- (D) Review grant and loan applications based on the criteria, requirements and standards adopted by the ICOC and make recommendations to the ICOC for the award of grants and loans to promote training, research, therapy development, and clinical trials;
- (E) Oversee peer-group reviews of grantees to ensure compliance with the terms of the award, and report to the ICOC any recommendations for subsequent action;
- (F) Recommend to the ICOC standards for the evaluation of grantees to ensure that they comply with all applicable requirements. Such standards shall mandate periodic reporting by grantees and shall authorize the SMRFWG to audit a grantee and forward any recommendations for action to the ICOC.

## **ARTICLE IV. SMRFWG Membership, Selection, and Terms of Service**

**Section 1 (Method of Appointment)** Members of the SMRFWG shall be appointed by the ICOC.

**Section 2 (Appointment).** The SMRFWG shall have 23 members composed of: (1) seven ICOC members from the ten (10) disease advocacy group members (“Patient Advocate Members”) described in paragraphs (3), (4), and (5) of subdivision (a) of Section 125290.20 of the Act; (2) fifteen (15) scientists (“Scientist Members”) nationally recognized in the field of stem cell research from institutions outside the State of California, and; (3) the Chairperson of the ICOC.

**Section 3 (Term of Service).** SMRFWG members shall normally serve for six (6) years except that after the first six-year term the members’ terms will be staggered so that one-third of the members shall be appointed for a term that expires two years later, one-third of the members shall be appointed for a term that expires four years later, and one-third of the members shall be appointed for a term that expires six years later. Subsequent terms are for six years. In the event that a SMRFWG member resigns prior to completing his or her term of service, incoming members appointed by the ICOC shall be invited to serve for a term of two (2), four (4), or six (6) years. SMRFWG members may serve a maximum of two consecutive terms.

**Section 4 (Expiration of Term).** When a member’s term expires, the ICOC shall appoint a new member within 30 days. SMRFWG members shall continue to serve until their replacements are appointed.

**Section 5 (Alternate Scientist Members).** Individuals with strong scientific expertise in stem cell research may be appointed by the ICOC to serve as Alternate Scientist Members of the SMRFWG. Alternate Scientist Members may serve in place of a Scientist Member of the SMRFWG who is unavailable to attend a meeting. Alternate Scientist Members have voting privileges in the SMRFWG and their presence is counted towards a quorum. In the event that a Scientist Member resigns from the SMRFWG, an Alternate Scientist Member may be confirmed by the ICOC as a replacement.

**Section 6 (Ad Hoc Members)** Individuals with strong scientific expertise in stem cell research or on a particular issue may be appointed by the ICOC to serve as Ad Hoc Members of the SMRFWG and may occasionally attend meetings of the SMRFWG when a Scientist Member is unavailable to attend a meeting. Ad Hoc members have voting privileges and their presence is counted towards a quorum.

**Section 7 (Specialists)** Individuals with scientific expertise on a particular issue may occasionally be invited to attend meetings of the SMRFWG for the purpose of providing evaluation or expertise with respect to specific grant(s) or research fields. Specialist members do not have voting privileges and their presence is not counted towards a quorum.

## **Section 8 (Chair of SMRFWG)**

- (A) **(Appointment)** The ICOC shall appoint a Scientist Member of the SMRFWG to serve as Chair of the SMRFWG.
- (B) **(Duties)** The Chair of the SMRFWG shall preside over the scientific evaluation of grants described herewith in Article VI, Section 2(A).

## **Section 9 (Vice-Chair of SMRFWG)**

- (A) **(Appointment)** The ICOC shall appoint as Vice-Chair of the SMRFWG a Patient Advocate member of the ICOC.
- (B) **(Duties)** The Vice-Chair of the SMRFWG shall preside over the grant and loan recommendation procedures described herewith in Article VI, Section 2(B).

## **Section 10 (Compensation and Expenses of SMRFWG Members).**

- (A) **ICOC Members** – Each member of the SMRFWG who is also an ICOC member, except the chairperson, shall receive a per diem of one hundred dollars (\$100) per day (adjusted annually for cost of living) for each day the member attends a SMRFWG meeting, plus reasonable and necessary travel and other expenses incurred in the performance of the member's duties. In addition, compensation in the amount of \$12.50 per hour shall be paid to ICOC members of the SMRFWG for time spent in preparation for a meeting of the SMRFWG.
- (B) **Non-ICOC Members** – Non-ICOC members of the SMRFWG shall be entitled to a daily consulting rate and reimbursement for expenses, as established by the ICOC.

**Section 11 (Conflict of Interest).** All non-ICOC members of the SMRFWG shall be governed by conflict of interest rules and economic disclosure requirements adopted by the ICOC. ICOC members shall be governed by California conflict of interest laws, as set forth in Health and Safety Code section 125290.30(g) and the conflict of interest policy for ICOC members adopted by the ICOC.

## **ARTICLE V. Duties of SMRFWG Members.**

**Section 1 (Scientist Members).** The fifteen (15) Scientist Members of the SMRFWG are responsible for evaluating and scoring grant and loan applications for scientific merit, and for recommending, along with the other members of the SMRFWG, grant and loan funding awards to the ICOC.

**Section 2 (Patient Advocate Members).** The seven (7) Patient Advocate members of the SMRFWG, together with the Scientist Members, are responsible for recommending grant and loan funding awards to the ICOC.

**Section 3 (Alternate Scientist Members).** At the discretion of staff, Alternate Scientist Members may serve as substitutes for SMRFWG Scientist Members when a Scientist Member cannot attend a SMRFWG meeting. Alternate Scientist Members shall perform the same duties as Scientist Members.

**Section 4 (Ad Hoc Members)** Ad Hoc members are responsible for attending meetings of the SMRFWG for the purpose of providing scientific expertise on a particular issue(s), area or field and, at the discretion of the staff, may serve as a substitute for a SMRFWG Scientist Member when a Scientist Member cannot attend a SMRFWG meeting. Ad Hoc members shall perform the same duties as Scientist Members.

**Section 5 (Specialists).** Specialists may be invited by the staff to participate in meetings of the SMRFWG for the purpose of providing scientific expertise on a particular issue(s), area, or field and/or for a specific grant application.

## **ARTICLE VI. Meetings.**

**Section 1 (Regular Meetings).** The SMRFWG shall hold at least four meetings per year, one of which will be designated as its annual meeting. The SMRFWG may hold additional meetings as the CIRM determines are necessary or appropriate. The annual meeting shall be attended in person by SMRFWG members, any Alternate Members, and any Specialist/Ad Hoc Members.

**Section 2 (Teleconference Meetings).** At the discretion of staff, members of the SMRFWG may participate in meetings of the SMRFWG, with the exception of the annual meeting, by teleconference, provided that the public has the opportunity to participate in public sessions of the SMRFWG that are conducted by teleconference. Significant medical needs of members of the SMRFWG will be given a high priority in arranging teleconference meetings.

**Section 3 (Open Meetings).** The SMRFWG shall meet in public session except for discussions related to evaluation of grant applications and recommendation of applications to the ICOC, discussions related to appeals of SMRFWG recommendations, discussions related to the review of a grantee's compliance with the terms of the award, and discussions of other matters that may be considered in closed session under the Bagley-Keene Open Meeting Act or under Health & Safety Code section 125290.30. The SMRFWG may recommend additional exceptions to the ICOC as necessary to carry out the mission of the SMRFWG.

**Section 4 (Special and Emergency Meetings).** Special and emergency meetings may be called by the Chair of the SMRFWG if necessary.

## **ARTICLE VII. SMRFWG Procedure for Recommending Grant and Loan Applications.**

**Section 1 (Quorum).** Sixty-five percent of the SMRFWG members who are eligible to vote shall constitute a quorum of the SMRFWG.

**Section 2 (SMRFWG Recommendation Procedures).**

(A) Unless excused due to conflicts, both ICOC and non-ICOC members of the SMRFWG shall be present in-person or via teleconference during the entire SMRFWG meeting, and may participate in all discussions.

**(B) Scientific Evaluation and Scoring**

1. The Chair of the SMRFWG shall preside over the scientific evaluation and scoring process.
2. The fifteen (15) Scientist Members of the SMRFWG shall evaluate each grant and loan application for scientific merit and assign a numerical value to each grant based on standards and criteria adopted by the ICOC. The criteria and standards for evaluation are hereby incorporated by reference into these Bylaws.
3. The average numerical score for each grant will be calculated and recorded as its scientific score.

**(C) Funding Recommendations**

1. Once grant and loan applications have been assigned a scientific score, all voting members of the SMRFWG shall place each grant and loan application into one of three categories by separate or by *en bloc* vote as appropriate:
  - a. **Recommended for Funding (Tier 1)** – Highly meritorious grant and loan applications that are recommended for funding to the ICOC.
  - b. **Recommended for Funding Pending Available Funds (Tier 2)** – Meritorious grant and loan applications that are recommended for funding to the ICOC pending available funds.
  - c. **Not Recommended for Funding (Tier 3)** – Grant and loan applications that are not sufficiently meritorious to be recommended for funding to the ICOC.
2. The SMRFWG may recommend partial funding of an application, if it determines that parts of an application are not sufficiently meritorious to be recommended for funding to the ICOC.

**Section 3 (Recommendations and Minority Reports).** Recommendations of the SMRFWG to the ICOC shall be made by a majority vote of a quorum of the members of the SMRFWG, except for recommendations involving “vital research opportunities,” which require a two-thirds vote of a quorum of the members of the SMRFWG pursuant to Health & Safety Code

section 125290.60(c)(1)(D). If thirty-five percent (35%) of the members of the SMRFWG join together in a minority position, a minority report may be submitted to the ICOC.

**Section 4 (Priority for Funding).**

- (A) The SMRFWG shall give priority to applications involving pluripotent stem cell and progenitor cell research that cannot, or is unlikely to receive timely or sufficient federal funding, unencumbered by limitations that would impede the research. Applications involving research categories funded by the National Institutes of Health shall not be recommended for funding pursuant to this subdivision.
- (B) Notwithstanding subdivision (A), the SMRFWG may recommend funding for vital research opportunities. A “vital research opportunity” means scientific and medical research and technologies and/or any stem cell research that is not recommended for funding pursuant to (A) of this section but which provides a substantially superior research opportunity vital to advance medical science as determined by at least a two-thirds vote of a quorum of the members of the SMRFWG. Human reproductive cloning shall not be considered a vital research opportunity.

**ARTICLE VIII. Rules of Order.**

Debate and proceedings in the SMRFWG shall be conducted in accordance with Robert’s Rules of Order (Newly Revised) when not in conflict with rules of the SMRFWG or other statutory requirements.

**ARTICLE IX. Amendments.**

These Bylaws may be amended or repealed by the ICOC at any regular or special meeting by a majority vote of a quorum of the ICOC. The SMRFWG may recommend amendments to these bylaws to the ICOC for its consideration.